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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/575,638	05/22/2000	Lisa Anne Laffend	CR9715 US DIV1	1504

23906 7590 05/23/2002

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EXAMINER	
BUGAISKY, GABRIELE E	
ART UNIT	**PAPER NUMBER**
1653	13

DATE MAILED: 05/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/575,638	LAFFEND ET AL.	
	Examiner	Art Unit	
	Gabriele E. BUGAISKY	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19 and 31-34* is/are pending in the application.

4a) Of the above claim(s) *19 and 34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18 and 31-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7 .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

Election/Restrictions

The Applicant's election of Group I in Paper No. 12 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 19 and 34 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

It is noted in the election of 3/17/02 that the Applicant's representative states that the preliminary amendment filed concurrently with the application deleted all field claims except for 2, 6, and 33, and added claim 34.

Line 17 of the patent application transmittal specifically states claims 20-30 are to be cancelled. Although the preliminary amendment states on page 2, lines 13-14 that claims 2, 6, 31 and 34 are pending, the Examiner can find no statement directing the PTO to cancel Claims 1, 3-5, 7-19 and 32-33. Until these claims are specially cancelled, they are presumed to remain pending.

Specification

The disclosure is objected to because of the following informalities: The ATCC deposit information on page 6, lines 27-28, 31-32, and 35-36 is blank, as well as that of page 7, lines 1-2, and 5-6. Further, the preliminary amendment (page 2) requested changes to page 50, lines 30

and 38 and to page 63, line 29, which were not entered, as ATCC deposit information was not on those lines. Lines 28 and 36 of page 50 and line e 17 page 63 require deposit information. Applicant is requested to confirm the amendatory material. .

Appropriate correction is required.

It is noted that statements of availability have been submitted for the deposited cell lines.

The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim 32 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 31. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-18 and 31-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-4 of U.S. Patent No. 6025184. Although the conflicting claims are not identical, they are not patentably distinct from each other because it is obvious to use the claimed microorganism of the patent .in a process of making propanediol since the exogenous genes enable the host to make propanediol.

With respect to claims 31-33, it is obvious to use the exogenous gene of the patented microorganism to transform yeast, as yeast are a common source for industrial production of chemical compounds.

Claim 6 is rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 and 13-16 of U.S. Patent No. 5,686,276 in view of Daniel *et al.*(1992), in light of Daniel *et al.* (1995). The claims of the patent are to a process for production of 1, 3-propane diol, with a substrate other than glycerol or dihydroxyacetone. They do not specify that the bacteria be transformed with an exogenous *dhaT* gene. Daniel *et al.* provides transformed *E. coli* which express the *Citrobacter freundii dha* regulon and produce active glycerol dehydratase; the presence of which is assayed by measurement of 1,3-propanediol production. They do not use a substrate other than glycerol or dihydroxyacetone. Daniel *et al.* later stated that the cosmid used in their earlier work which contained the *dha* regulon also contained the 1, 3-propanediol dehydrogenase gene (*dhaT).*

In order to produce 1, 3- propane diol, with a substrate other than glycerol or dihydroxyacetone, it would have been obvious to use the transformed *E. coli* of Daniel *et al.* in the process of U.S. Patent No. 5,686,276, with a reasonable expectation of success in obtaining 1, 3- propane diol.

Claims 1-18 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 14-19,21, 25, 28 and 30 of claims 1-10 of U.S. Patent No. 5821092. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope. The independent claims of the instant application are directed to a process using microorganisms having a dehydratase gene, whereas those of the copending application are drawn solely to microorganisms transformed with a dehydratase gene.

Claims 1-18 and 31-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope and are drawn to genes on the same cosmid and transformed organisms containing genes of the cosmid.

With respect to claims 1-18 and 33 because it is obvious to use the claimed microorganism of the patent .in a process of making propanediol since the exogenous genes enable the host to make propanediol.

Claims 1-18 and 31-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,633,362. Although the conflicting claims are not identical, they are not patentably distinct from each other because they differ merely in scope.

Claims 1-18 and 31-33 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-133 of U.S. Patent No. 6013494. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant application states at least one exogenous gene encoding a glycerol dehydratase be used, whereas the claims of the patent state that at least one four specifically recited genes including a dehydratase gene is used.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-12,14-18 and 31-33 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a process of generating 1, 3, propane diol with microorganisms transformed with the *Klebsiella pneumoniae dhaB* gene, does not reasonably provide enablement for production of 1, 3 propane diol by any microorganisms transformed with any diol dehydratase gene from any other organism. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims. The instant application shows the production of 1, 3, propane diol from organisms transformed with the glycerol dehydratase gene of *Klebsiella pneumoniae*, but does not address how to purify or isolate any other dehydratase genes from any other organism. No teaching is given regarding sequence similarity either between *dhaB* genes of different organisms or between dehydratase genes in general. Furthermore, the specification fails to teach any other dehydratase that can be used to generate 1, 3, propane diol; the diol dehydrase of Tobimatsu *et al* , for example, catalyzes the conversion of 1, 2 diols to the corresponding aldehydes and is not known to produce 1, 3, propanediol. The specification does not teach how one may use such an enzyme in the claimed process. It is deemed that the scope of the claims is much broader than the enablement provided by the specification and that undue experimentation would be involved in obtaining other dehydratase genes with which to practice the claimed invention.

Claims 5, 6, 12 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 5, presumably "gylcerol" should be "glycerol".

It is confusing in claim six as to what genes the DNA fragment may contain. Does the fragment encode one of *dhaB1, dhaB2* . . . or must it contain *dhaB1-B3*?

In claim 12, line 2, presumably "cerevisiase" should be "cerevisiae".

Claim 14 is presently confusing. The recited limitation that the carbon substrate has at least a single carbon atom is no limitation, as a molecule lacking a single carbon atom is not a carbon substrate.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5-10, 18, and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Daniel *et al.* The reference is anticipatory because it provides transformed *E. coli* which express the *Citrobacter freundii dha* regulon and produce active glycerol dehydratase. The presence of the recombinantly produced enzyme is assayed by measurement of 1,3-propanediol production.

Conclusion

No claims are allowed.

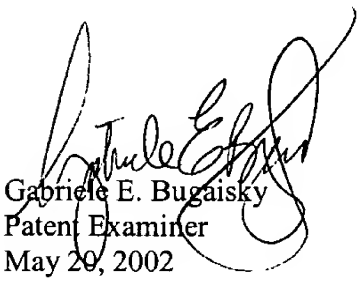
The art made of record and not relied upon is considered pertinent to applicant's disclosure DI AZ-TORRE *et al.* disclose a method for production of 1-3 propanediol using recombinant microorganisms.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Gabriele E. Bugaisky, Ph.D. whose telephone number is (703) 308-4201. The Examiner can normally be reached from 8:15 AM to 12:15 PM on Mondays and from 8:15 AM to 1:15 PM on other weekdays.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher S. F. Low, can be reached at (703) 308-2923.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center receptionist whose telephone number is (703) 308-0196.



Gabriele E. Bugaisky
Patent Examiner
May 20, 2002

GABRIELLE BUGAISKY
PATENT EXAMINER